PATENT

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the Application of:	GANTZ *et al.*
SERIAL NO.:	10/518,811
Filed:	July 11, 2005
Entitled:	**COCHLEAR IMPLANT ELECTRODE ARRAY**
Docket No.:	22409-00113-US

Group Art Unit: 3766
Examiner: WU, Eugene Tong

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is Cochlear Limited of Australia. Cochlear Limited derives its rights in this application by virtue of assignments of the application to Cochlear Limited.

II. RELATED APPEALS AND INTERFERENCES

None

III. STATUS OF CLAIMS

Claims 1-4, 6, 8-10, 12, 13, 22-25, and 36-43 are currently pending in the present application, Application Number 10/518,811. Claims 5, 7, 11, 14-21, 26-35 were previously cancelled. Claims 1-4, 6, 8-10, 12, 13, 22-25, and 36-43 have been finally rejected and, therefore, are subject to appeal.

IV. STATUS OF AMENDMENTS

All Amendments have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to an implantable electrode array 30 comprising an elongate carrier 31 having a plurality of electrodes 32 disposed therein. (*See*, independent claim 1; Specification, pg. 17, ll. 14-15.) Implantable electrode array 30 is configured to be inserted through an insertion point on the cochlea. (*See*, independent claim 1; Specification, pg. 17, ln. 33.) A stabilizing collar 35 has an abutment surface 37 for abutting a surface of and outside the cochlea, and an anchor 36 embedded within collar 35 which is configured to prevent translation

by the array along, and rotation about, a longitudinal axis of carrier 31. (*See*, independent claim 1; Specification, pg. 17, ll. 24-28; Specification, FIG. 2A.)

In one embodiment of the invention, anchor 36 is a Dacron mesh and is used to anchor or fix the array to the promontory bone. (*See*, Specification, pg. 17, ll. 27-28, 34-35.) Over time, the mesh becomes integrated with the surrounding fibrous tissue. (*See*, Specification, pg. 17, ll. 27-28, 34-35.) By abutting collar 35 against the cochlea surface outside the insertion point, and by anchoring Dacron mesh 36 on the promontory bone, electrode array 30 is prevented from rotating (because of the anchored Dacron mesh) and from moving further into our out of the insertion point at the cochlea (because of the abutting collar). (*See*, Specification, pg. 18, ll. 1-3.) In Applicant's claimed invention, the anti-rotation and anti-translation benefits are provided by the stabilizing collar and the anchor disposed therein. (*See*, independent claim 1.)

Independent claim 22 is directed to a method of inserting an implantable electrode array 30 into a recipient's cochlea. (*See*, independent claim 22.) The array 30 has a collar 35 with an abutting surface 37 and an anchor 36 attached to collar 35. (*See*, independent claim 22.) The method comprises forming an opening in the cochlea, inserting and advancing array 30 through the formed opening, abutting (via abutting surface 37) against the tissue surrounding the opening, and securing array 30 (via anchor 36) to prevent its translation and rotation movement about the longitudinal axis of the array. (*See*, independent claim 22.) By abutting collar 35 against the tissue around the insertion point, and by securing array 30 with anchor 36, electrode array 30 is prevented from rotating (because of anchor 36) and from moving further through the insertion point into the cochlea (because of the abutting collar). (*See*, Specification, pg. 18, ll. 1-3.)

Independent claim 38 is directed to an implantable electrode array 30 for inserting, via an insertion point, into a cochlea comprising means for abutting array 30 against tissue around the insertion point and means for anchoring the abutting means to the cochlea. (*See*, independent claim 38.) By abutting collar 35 against the cochlea surface outside the insertion point, and by anchoring it to the cochlea, electrode array 30 is prevented from rotating (because of the anchored Dacron mesh) and from moving further through the insertion point into the cochlea (because of the abutting collar). (*See*, Specification, pg. 18, ll. 1-3.) In Applicant's claimed invention, the anti-rotation and anti-translation benefits are provided by a single "means for anchoring said abutting means to the surface of the cochlea… to prevent translation… along and rotation about… a longitudinal axis of the array." (*See*, independent claim 38.)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether the Examiner improperly rejected independent claims 1, 22 and 38 and dependent claims 2-4, 6, 8-10, 13, 25, 36, 37, 39, and 41-43 under 35 U.S.C. § 103(a) as unpatentable over WO00/69513 to Kuzma in view of U.S. Patent No. 5,143,090 to Dutcher.

VII. ARGUMENT

A. Kuzma already provides the benefits provided by the mesh of Dutcher, and there is no motivation to add the mesh to the Kuzma device

In the Office Action mailed October 4, 2007, the Examiner rejected independent claims 1, 22 and 38 under 35 U.S.C. § 103(a) as being unpatentable over WO00/69513 to Kuzma ("Kuzma") in view of U.S. Patent No. 5,143,090 to Dutcher ("Dutcher"). For at least the reasons

provided below, the combination of Kuzma nor Dutcher is prima facie improper in rejecting claims 1, 22 or 38, and, as such, the rejections should be reversed.

To establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Furthermore, as noted in the MPEP, "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)." (*See*, Manual of Patent Examining Procedures, §2143.02.)

Regarding the combination of references the result of which is relied upon in a finding of obviousness, the MPEP guides:

> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
>
> (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention;

(*See*, Manual of Patent Examining Procedures, §2141, "Basic Considerations Which Apply To Obviousness Rejections".)

Kuzma describes a first structure (tines 16 and shoulder 19) used to fix the array to the target tissue, which prevents movement deeper into our out of the cochlea at the insertion point. Kuzma states that "electrode array 10 is inserted through the slit 42 until the flaps or tines 16 have passed through the slit into the basal region 34, and the shoulder 19, formed by the head 18, rests agains the middle-ear side of the round window membrane 40… [T]he flexible flaps or tines 16, once passed through the slit 42, prevent the electrode array from slipping out of the slit 42… Thus, it is seen that array 10 is held in position within the basal region 34 by the shoulder 19, and flaps or tines 16." (*See*, Kuzma, pg. 8, ll. 13-16, 21-22; FIGS. 1A and 2, reproduced below.)

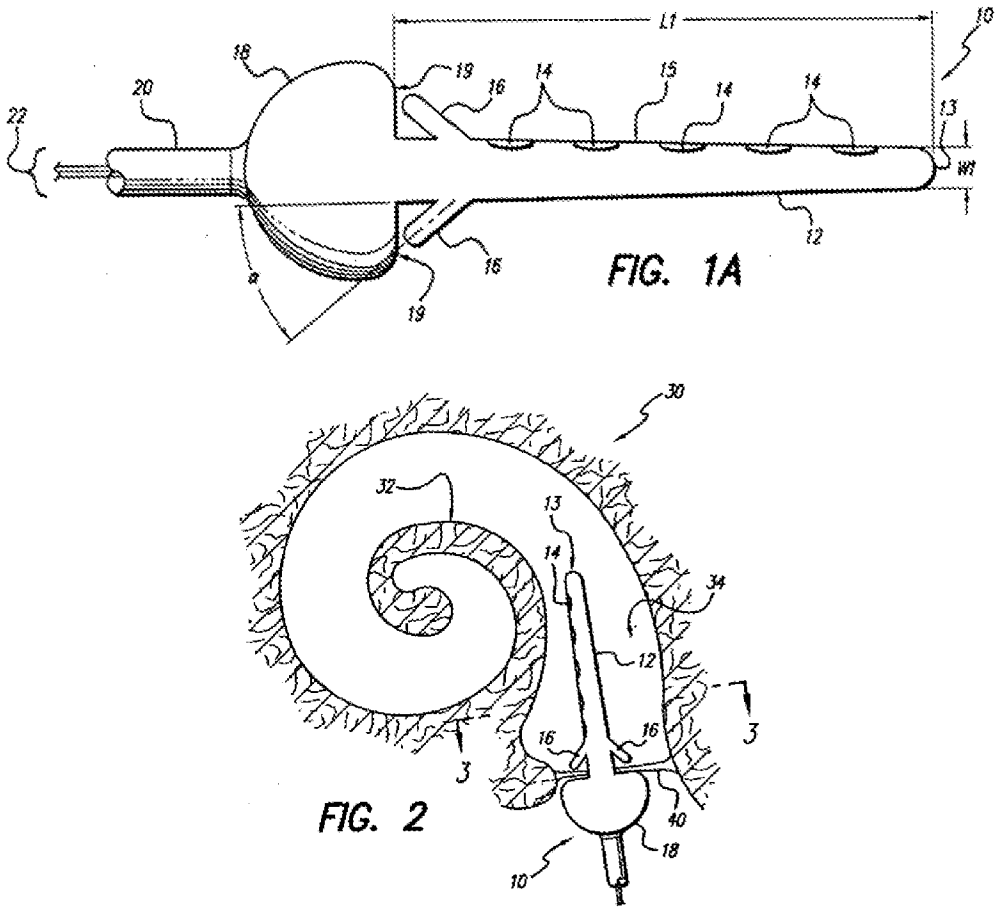


FIG. 1A and 2 of Kuzma

Kuzma also describes a second structure (flat-shaped electrode array 10 inserted through flat slit 42) used to also fix the array to the target tissue, which prevents rotational movement. (*See*, Kuzma, FIG. 2, above.) Kuzma states that "because the electrode array 10 is 'flattened', or pancake shaped (when viewed in cross section as seen in FIG. 3), the distal tip 13 and the rest of the array 10 readily slide through the slit 42. The slit 42 advantageously maintains the medial side of the array 10 facing in the right direction." (*See*, Kuzma, pg. 8, ll. 24-27; FIGS. 1A-1B, reproduced below.)

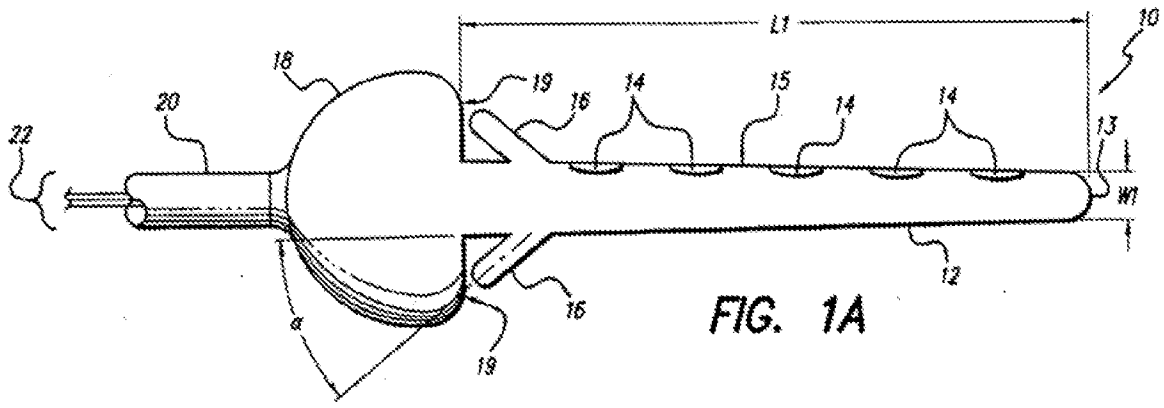


FIG. 1A

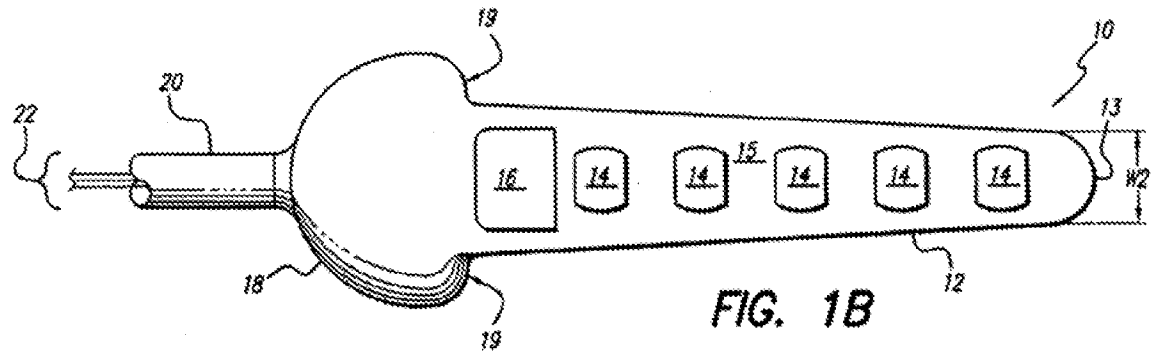


FIG. 1B

FIGS. 1A and 1B of Kuzma

The "slit 42" in Kuzma refers to a slit "made in the round window membrane 40", as illustrated in FIG. 4 of Kuzma. (*See*, Kuzma, pg. 8, ll. 12-13; FIG. 4 reproduced below.)

Clearly, Kuzma discloses that the array is fixed in place by the "flattened" and "pancaked" shape of array 10 inserted into the "slit" that has been surgically made in the round window membrane of the patient. (*See*, Kuzma, FIGS. 1A, 1B, above, and FIG. 4, below.) This flat array in cooperation with flat slit 42 is described in Kuzma as also fixing the array to the tissue and preventing rotation by the flat array device.

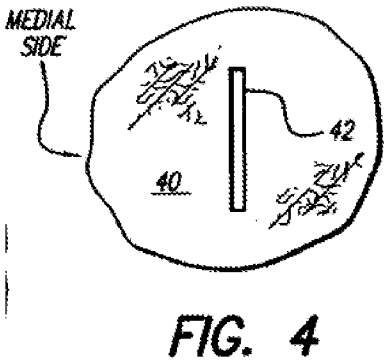


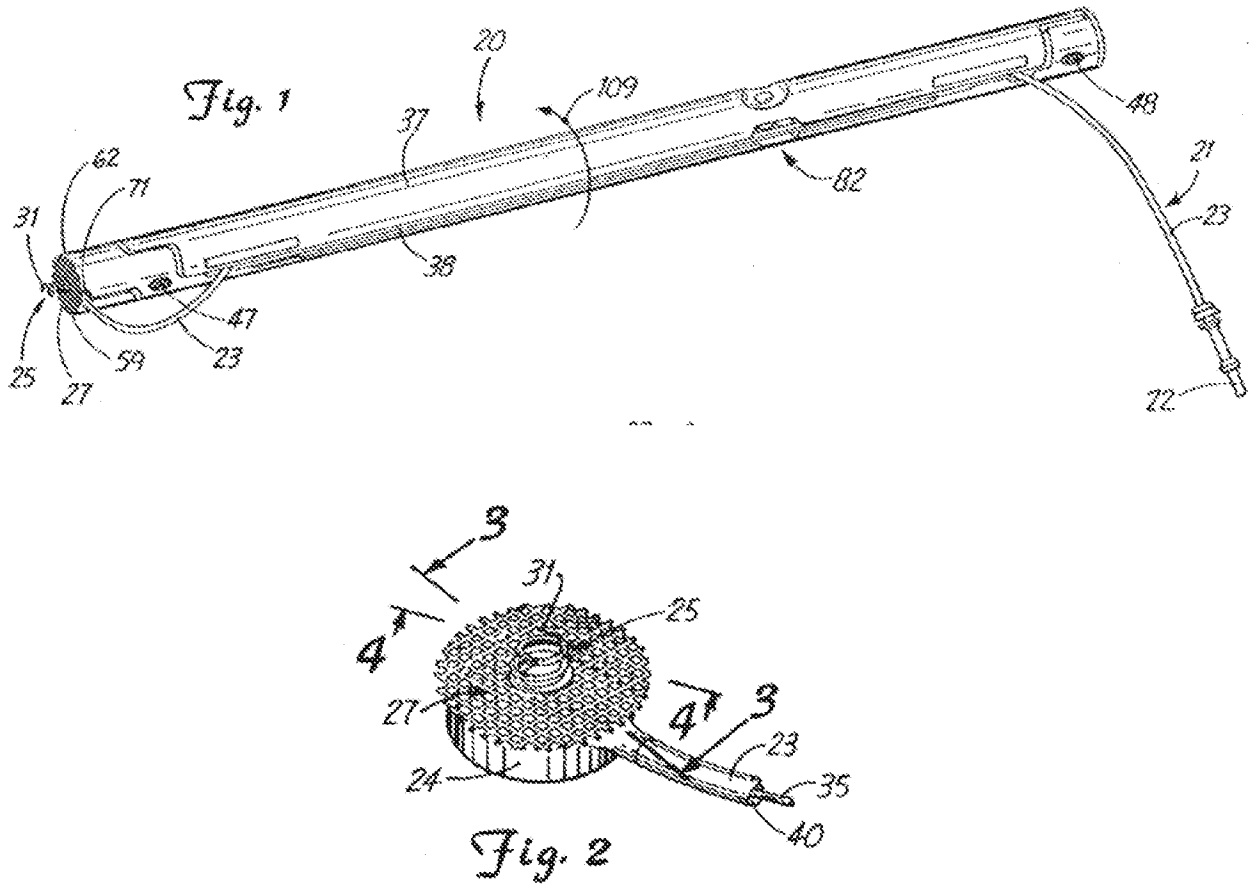
FIG. 4

FIG. 4 of Kuzma

Therefore, in Kuzma, the array is already firmly fixed by shoulder 19 and flaps/tines 16, which prevents translation, and by the combination of the surgical slit 42 working with the flat-shaped array 10, which prevents rotation.

Dutcher describes a cardiac lead 21 held by an insertion tool 20. (*See*, Dutcher, col. 3, ll. 52-54; FIG. 1, reproduced below.) The distal end of insertion tool 20 is shown in FIG. 2 of Dutcher, reproduced below. Head 24 has embedded therein electrode 25. (*See*, Dutcher, col. 3, ll. 65-68.) "A generally flat circular netting 27 surrounds electrode 25… to increase the surface

engagement with the heart tissue. Netting 27 can be porous polyester fiber that enhances fibroic growth to insure a secure connection of electrode 25 to the heart tissue." (*See*, Dutcher, col. 4, ll. 5-14.)



FIGS. 1 and 2 of Kuzma

The Examiner justifies the asserted combination of Kuzma with Dutcher by stating that "the combination of Kuzma with Dutcher as proposed… is not motivated by providing an anti-rotation design, but rather to enhance tissue ingrowth to firmly fix the lead to target tissue, which happens to also prevent rotation." (*See*, Advisory Action, mailed January 31, 2008, continuation

sheet.) The Examiner also asserts that the proposed combination would provide an "even more secure electrode arrangement than the flaps and shoulder of Kuzma alone." (*See*, Advisory Action, mailed January 31, 2008, continuation sheet.)

The benefits attained by an ingrowth of tissue produced by the mesh, which the Examiner seeks to add to the Kuzma device, is already achieved by the device of Kuzma without the added mesh and associated ingrowth of tissue. Kuzma already describes firmly securing the array so as to both prevent rotation and translation along the longitudinal axis of its array. Therefore, one of ordinary skill in the art would not have been motivated to make the combination suggested by the Examiner based on a desire to firmly fix the lead to the target tissue, since that is already being allegedly done by Kuzma. The Examiner's adding to an otherwise complete reference with respect to an anti-rotation feature by suggesting the adding of what amounts to a redundant anti-rotation feature from Dutcher can only be viewed as a use of impermissible hindsight, contrary to the requirements of the MPEP, for example, as quoted above. Accordingly, Applicants assert that this rejection of these claims is improper and respectfully request that it be reconsidered and withdrawn.

As Kuzma already suggests securing or firmly fixing the lead to the target tissue, one of ordinary skill in the art would not have been motivated to seek out Dutcher to find a device to "firmly fix the lead to target tissue" as alleged by the Examiner. (*See*, Office Action, pg. 3, ¶ 7.)

As such, for at least similar reasons to those discussed above, no proper motivation exists for combining Kuzma with Dutcher and the rejection of these claims based on the improper combination fails to *establish prima* facie obviousness as is required by the MPEP. Applicants,

therefore, respectfully submit that the rejections of independent claims 1, 22 and 38 are improper and should be withdrawn.

B. The Examiner renders the prior art invention unsatisfactory for its intended purpose, contrary to MPEP §2143.02

The MPEP makes clear, "If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." (*See*, Manual of Patent Examining Procedures, §2143.02.) As described below, the Examiner's suggested combination would effectively prevent the provided structures (tines and flat-array) in Kuzma from serving their intended purpose of fixing its array in place (thereby providing anti-translation and anti-rotation effects).

As noted, Kuzma describes tines 16 and shoulder 19 used to fix the array to the target tissue, which prevents movement deeper into or out of the cochlea at the insertion point as well as the Kuzma array having a "pancake shaped" configuration which is inserted through flat slit 42 for the specific purpose of preventing rotational movement. (*See*, Kuzma, FIG. 2, reproduced above.)

By combining the mesh feature from Dutcher "for the purpose of enhancing tissue ingrowth to firmly fix the lead to target tissue", the resulting device would negate the purpose of the tines and flat-shaped array, since the function performed by those features would then be performed completely by the added mesh feature. (*See*, Office Action, pgs. 3-5, paragraph 7.) That is, if the mesh which the Examiner suggests be added to Kuzma is added and used as

suggested, the array to which it is attached would be prevented from moving laterally or rotationally by the mesh alone, making the tines and flat shape of the array purposeless. This is clearly contrary to the MPEP as quoted above.

C. Substantial modifications are needed to Kuzma in order to combine it with Dutcher

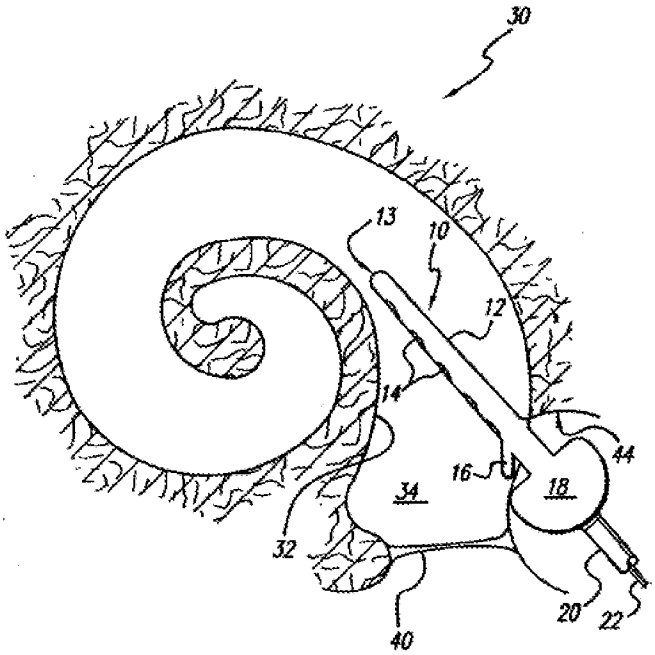


FIG. 5

FIG. 5 of Kuzma

Finally, it should be noted that the MPEP provides, "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima

facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)." (*See*, Manual of Patent Examining Procedures, §2143.02.)

Even were the Examiner's assertions as to the motivation of combining Kuzma with Dutcher proper, Kuzma would need to be substantially modified in order for the combination to work. For instance, as noted, Kuzma is configured to prevent translation using the tines or protuberances 16 and shoulder 19 of FIG. 2, and to prevent rotation using the cooperation of flat array 12 and slit 42 of FIGS. 2 and 4. It is unclear where an anchor such as the mesh from Dutcher would be placed on the Kuzma device. Assuming for the sake of argument that it could be mounted on shoulder 19, when the Kuzma device is inserted at an angle, as shown in FIG. 5 of Kuzma, the full surface of shoulder 19 does not even contact the round window membrane 40. In that case, the anchor added to shoulder 19 of Kuzma would not be in contact with round window membrane 40 so as to be able to prevent rotation unless tines 16 are removed/modified and shoulder 19 redesigned so that an anchor on shoulder 19 is in contact with round window membrane 40 (*e.g.*, by increasing the thickness of a portion of shoulder 19).

For the reasons noted above, Applicant submits that the pending claims define patentable subject matter. Accordingly, Applicant request that the Examiner's rejections of these claims be reversed and that the pending application be passed to issue.

Dated: June 4, 2008

Respectfully submitted,

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CLAIMS APPENDIX

1. An implantable electrode array for insertion through an insertion point into at least the basal region of the cochlea, the array comprising:

an elongate carrier having a longitudinal axis;

a plurality of electrodes disposed in said carrier; and

stabilizing collar disposed adjacent to said carrier comprising:

an abutment surface configured to abut a surface of the cochlea adjacent the insertion point; and

at least one anchor configured to substantially prevent translation along, and rotation about, the longitudinal axis of said carrier.

2. The implantable electrode array of claim 1, wherein said collar comprises:

a first collar portion having a diameter greater than that of said carrier.

3. The implantable electrode array of claim 1, wherein said collar comprises a distal end connected to said carrier, and wherein said abutment surface is disposed on said distal end of said collar.

4. The implantable electrode array of claim 3, wherein said abutment surface extends outwardly from said carrier at a substantially right angle to the longitudinal axis of said carrier.

5. (Cancelled)

6. The implantable electrode array of claim 1, wherein said collar is formed integrally with said carrier.

7. (Cancelled)

8. The implantable electrode array of claim 1, wherein said anchor is disposed adjacent to said.

9. The implantable electrode array of claim 1, wherein said anchor comprises a mesh configured to be sutured to a recipient thereby affixing said anchor to the recipient.

10. The implantable electrode array of claim 9 wherein said mesh is formed integrally with said collar.

11. (Cancelled)

12. The implantable electrode array of claim 1 further comprising:

at least one indicator disposed on said collar configured to indicate rotational orientation of the electrode array.

13. The implantable electrode array of claim 1 wherein the array is configured for inserting to approximately a first turn in the basal region of the cochlea.

14-21. (Cancelled)

22. A method of inserting an implantable electrode array into at least the basilar region of the scala tympani duct of a recipient's cochlea, the electrode array comprising a collar comprising an abutting surface on the array and at least one anchor attached to the collar and the array, the method comprising the steps of:

forming an opening in the cochlea;

inserting said array into the cochlea and advancing the array therein; and

abutting said abutting surface on said collar means to the tissue surrounding said opening formed in the cochlea; and

securing the electrode array to prevent translation along, and rotation about, a longitudinal axis of the electrode array.

23. The method of claim 22, further comprising:

fabricating a fascia washer using the recipient's tissue; and

positioning the fabricated washer over the array before said inserting into the cochlea.

24. The method of claim 23, wherein the fascia washer comprises temporalis fascia tissue harvested from the recipient.

25. The method of claim 22, wherein securing the array further comprises:

the at least one anchor to the recipient adjacent the formed opening.

26-35. (Cancelled)

36. The method of claim 22, wherein the collar further comprises an indicator disposed therein, the method further comprising:

orienting the array during said inserting with respect to the cochlea using the indicator.

37. The method of claim 22, wherein inserting said electrode array into the cochlea further comprises:

halting said inserting when a distal end of the array is at the first basilar turn of the cochlea.

38. An implantable electrode array for insertion through an opening at an insertion point into at least the basal region of the cochlea, the array comprising:

means for abutting configured to abut the array against a surface of the cochlea adjacent the insertion point; and

means for anchoring said abutting means to the surface of cochlea adjacent the insertion point to prevent translation along, and rotation about, a longitudinal axis of the array.

39. The implantable electrode array of claim 38, wherein said means for anchoring the array is configured as a mesh.

40. The implantable electrode array of claim 38, further comprising:

means for orienting the array with respect to the cochlea.

41. The implantable electrode array of claim 1, wherein said abutment surface is further configured to seal the cochlea at the insertion point.

42. The method of claim 22, wherein abutting said abutting surface further comprises:

sealing the opening in the cochlea with said abutting surface.

43. The implantable electrode array of claim 38 wherein said means for abutting is further configured to seal the cochlea opening at the insertion point.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None